K121047

OCT 4 2012

# 510(k) Summary

This summary of 510(K) – safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 07/31/2012

1. Submitter

| | Submitter |
|---|---|
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2. U.S Agent/Contact Person

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3. Device

Trade Name: Hero II Dental Implant System
IS Dental Implant System
Common Name: Dental Implant
Classification Name: Endosseous Dental Implant System
Product Code: DZE, NHA
Classification regulation: 21CFR872.3640

2. Predicate Device:

GS FIXTURE SYSTEM by OSSTEM IMPLANT CO., LTD (K072896)

3. Description:

The Hero II Dental Implant system and the IS Dental Implant System are dental

implant systems made of Titanium 6AL 4V ELI alloy intended to be surgically placed in the bone of the upper or lower jaw arches for loading after a conventional healing period. The implants may be used to replace one or more missing teeth. The systems are similar to other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics. The surface of these systems have been treated with R.B.M (Resorbable Blast Media). The size information is as below.

**Hero-II Fixture**

Ø 3.75mm x (L) 8.5mm, 10.0mm, 11.5mm, 13.0mm, & 15mm
Ø 4.00mm x (L) 8.5mm, 10.0mm, 11.5mm, 13.0mm, & 15mm
Ø 4.50mm x (L) 8.5mm, 10.0mm, 11.5mm, 13.0mm, & 15mm
Ø 5.00mm x (L) 8.5mm, 10.0mm, 11.5mm,13.0mm, & 15mm
Ø 6.00mm x (L) 8.5mm, 10.0mm, 11.5mm,13.0mm, & 15mm

**IS Fixture**

Ø 3.75 x (L) 8.5mm, 10.0mm, 11.5mm, & 13.0mm
Ø 4.0 x (L) 7.3mm, 8.5mm, 10.0mm, 11.5mm, & 13.0mm
Ø 4.5 x (L) 7.3mm, 8.5mm, 10.0mm, 11.5mm, & 13.0mm
Ø 5.0 x (L) 7.3mm, 8.5mm, 10.0mm, 11.5mm, & 13.0mm
Ø 6.0 x (L) 7.3mm, 8.5mm, 10.0mm, 11.5mm, & 13.0mm

**Abutments**

Diameter Ø4mm ~ Ø7mm
Cuff height 1~4mm
Height 4~7mm

4. Indication for use:

The Hero II Dental Implant System and the IS Dental Implant System are indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The Hero II Dental Implant System and IS Dental Implant System are for single and two stage surgical procedures. These systems are intended for delayed loading.

5. Basis for Substantial Equivalence

The Hero II Dental Implant system and the IS Dental Implant system have the same intended use as the identified predicate device (K072896). The Hero II / IS Dental Implant system and GS FIXTURE SYSTEM are similar in fundamental scientific technology in that they are all threaded, root form implants constructed of titanium with RBM roughened surfaces. They all share same internal hexagon abutment connection system with internal beveled interface. The subject and predicate devices are both bone-level implants that share similar body shape design such as straight walled neck and tapered body design.

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The subject and predicate devices are similar in size, materials, surface treatment, and are sterilized via gamma irradiation for fixtures.

6. Non-Clinical Testing

- Sterilization validating testing has been performed in accordance with ISO 11737-1 & ISO 11737-2 for gamma sterilization and ISO 17665-1 and ISO 17665-2 for steam sterilization.
- The three year of shelf life has been validated through accelerating testing.
- Chemical and SEM image analyses have been performed to verify that there is no residual after RBM treatment on the fixtures.

7. Conclusion

The subject devices and the predicate device have the same intended use and have the same technological characteristics. The subject and predicate implants are all made of commercially pure titanium and have the same surface treatments.

Overall, the Hero II Dental Implant system and the IS Dental Implant system have the following similarities to the predicate device:

* have the same intended use,
* use the same operating principle,
* incorporate the same basic design,
* incorporate the same material and the surface treatment.

Based on the similarities, we conclude that the Hero II Dental Implant system and the IS Dental Implant system are substantially equivalent to the predicate device.

**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 4 2012

KJ Meditech Company, Limited
C/O Ms. Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group
951 Starbuck Street, Unit J
Fullerton, California 92833

Re: K121047
Trade/Device Name: Hero II Dental Implant System
IS Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: September 26, 2012
Received: September 27, 2012

Dear Ms. Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

**510(k) Number (if known):** K121047

**Device Name:** Hero II Dental Implant System
IS Dental Implant System

**Indications For Use:**

The Hero II Dental Implant System and the IS Dental Implant System are indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The Hero II Dental Implant System and the IS Dental Implant System are for single and two stage surgical procedures. These systems are intended for delayed loading.

**Prescription Use** __√__ **AND** **Over-The Counter Use**_____
**(Per 21 CFR 801 Subpart D)** **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K121047